

## EXHIBIT “B”

# The Use of Vanilla in Ice Cream

## Rules, Regulations and Interpretations - All Are Needed For A Thorough Understanding

J. Mark Black, Ph.D.

Spectra Flavor & Fragrance Research, LLC  
7251 Paulsen Drive, Eden Prairie, MN 55346  
mark.black@earthlink.net  
952-294-0277



Much of the world loves vanilla ice cream. The flavor profile is intense enough to stand on its own, yet also is compatible with many other dessert foods. Indeed, it is the most popular flavor of ice cream in the world today, with more than a quarter of total ice cream market<sup>1</sup>. Most ice cream consumption is concentrated in North America, Europe and Australia with the United States leading all countries with about a quarter of the total consumption<sup>2</sup>. The market for frozen dairy confections in Asia is still relatively small but is rapidly growing, particularly the super-premium vanilla ice cream segment.

From a regulatory standpoint, vanilla is handled similarly to other flavors throughout most of the world. Country or region-specific flavor regulations apply to vanilla just like any other flavor. Thus, vanilla frozen confections manufactured for use outside the U.S. generally use conventional flavor nomenclature when naming their products. The U.S. flavor rules define vanilla flavor in a manner similar to the rest of the world (21 CFR 1:101.22, see Appendix A for full text) and these rules suffice for most products. The flavor rules also apply to vanilla used as a non-characterizing flavor in frozen dairy confections, such as in chocolate and strawberry ice creams. However, the flavor rules do not apply to vanilla used as a characterizing flavor in thus-named vanilla and vanilla-flavored ice creams.

There has been longstanding confusion within the U.S. food industry about how vanilla is defined for use in vanilla ice cream products. This is because the U.S. Code of Federal Regulations<sup>3</sup> (CFR) defines vanilla extract and frozen dairy confections as foods with standards of identity. Standards of identity are designed to assure consumers they are receiving products that contain the components they believe they are purchasing. This is conveyed through the product name on the principal display panel. Implicit in the term "Vanilla Ice Cream" is that the product contains the familiar ingredients of cow's milk, cream, sugar and vanilla extract. The CFR, through legal interpretations, has woven together the vanilla extract standards and the ice cream product standards so that they cannot be separated as the regulations stand today.

Because of its standard of identity, vanilla extract and related products are handled under a separate section of the CFR (21 CFR 1:169, see Appendix B for full text). This section clearly defines vanilla as the alcoholic extraction (35% v/v) of properly cured and dried pods of either *Vanilla planifolia* Andrews or *Vanilla tahitensis* Moore species. The ratio of dried pods (25% moisture) to 35% v/v ethanol is one pound/gallon. All folded vanilla products, extracts, concentrates, oleoresins and powders are based on this primary definition of vanilla extract. There are no requirements for standardization of vanillin content or flavor profile for vanilla extract.

The frozen confection standards are defined in a third section of the regulations (21 CFR 1:135, see Appendix C for full text). The CFR establishes a three-tiered nomenclature system for the principal display panel, specifically for vanilla

and vanilla-flavored frozen dairy confections, based on the amount of natural flavor a product contains.

Category I: "Vanilla Ice Cream" contains no artificial flavor.

Category II: "Vanilla Flavored Ice Cream" contains a predominating, characterizing natural flavor and an artificial flavor simulating it.

Category III: "Artificially Flavored Vanilla Ice Cream" contains a predominating artificial flavor, used in combination with a natural flavor, or used alone.

The ice cream nomenclature rules, on their own, provide great latitude, thus confusion, in their interpretation. For example, the statement that Vanilla Ice Cream (Category I) contains no artificial flavor could be interpreted as the same as a natural flavor, as defined in the flavor rules (21 CFR 1:101), which can be compounded from natural flavor components obtained by different extraction and synthetic methods. For Vanilla Flavored Ice Cream (Category II), the CFR is not clear on what constitutes a "predominating" flavor; whether a flavor predominates by flavor intensity or by quantity. Because vanilla is a defined food, the CFR links the ice cream rules (21 CFR 1:135) to the vanilla rules (21 CFR 1:169) through the three-tiered nomenclature. However, the CFR does not call this out in the ice cream rules. Indeed, vanilla extract is not mentioned in any other part of the ice cream rules.

The industry sought clarification of these rules from the U.S. Food and Drug Administration (FDA). From 1979 to 1983, the FDA provided interpretations and ultimately an advisory opinion that clarified the rules around each category. However these have not been widely circulated, thus many ice cream manufacturers continue to be unsure about the legal status of their principal display panels.

The FDA clarified the use of natural flavor in Category I Vanilla Ice Cream in an interpretation issued to Mr. Glenn P. Witte of the International Association of Ice Cream Manufacturers<sup>4</sup>. Mr. Witte had requested clarification on the labeling of ice cream containing naturally derived non-vanilla bean flavoring compounds to enhance, simulate and/or intensify flavor derived from vanilla beans. This type of flavor is commonly called a vanilla WONF (with other natural flavors). Taylor Quinn (Associate Director for Compliance, Bureau of Foods, FDA) stated that "the labeling requirements for the declaration of flavors in the name of ice cream are specifically provided for by the standard. The general flavor regulations are not applicable to this standardized food." He summarized his opinion, saying "...the historical and current interpretation I believe is that the flavor agent for vanilla ice cream (a category I product) is limited to vanilla bean and/or flavor derived from vanilla beans." He further states "natural flavoring compounds that resemble, simulate and/or enhance vanilla flavor but are not derived from vanilla beans... would not comply with the intent of the flavor provisions of Category I ice cream." Therefore, the Quinn opinion clearly states that only vanilla from vanilla beans



can be used for Category I Vanilla Ice Cream. Vanilla WONF cannot be used at any level to maintain Category I status.

The FDA clarified the Category II status in an opinion written to Mr. Daniel P. Thompson<sup>5</sup>. Mr. Thompson's question concerned the use of an artificial flavor in combination with vanilla and vanillin. R.E. Newberry (Assistant to the Director, Division of Regulatory Guidance, Bureau of Foods) stated: "The ice cream standard under 21 CFR 135.110(e)(5)(I) states that an artificial flavor simulating the characterizing flavor shall be deemed to predominate in the case of vanilla beans or vanilla extract used in combination with vanillin, if the amount of vanillin used is greater than one ounce per unit of vanilla constituent as that term is defined in 169.3(c). Consequently, an ice cream manufacturer could not call his product 'vanilla flavored ice cream' (Category II) if the flavor consisted of one ounce of vanillin per unit of vanilla constituent and any flavor from a non-vanilla bean source (which simulates, resembles, or reinforces the vanilla flavor) is added to the product. *The non-vanilla flavor is deemed to simulate vanilla if the addition of the non-vanilla flavor results in a reduction in the amount of vanilla bean derived flavor that would otherwise be used in a vanilla flavored ice cream. Ice cream made from such a product would come under category III and have to be labeled as 'artificial vanilla.'*"

Newberry's logic can be extended also to Category I vanilla ice cream. His statement, that any flavor is characterizing that allows reduction of the amount of vanilla bean derived flavor in finished product, means that "non-characterizing" natural flavors cannot be added to Category I vanilla ice cream if their addition results in a reduction of vanilla extract. The product would be classified as Category II Vanilla Flavored Ice Cream. Newberry also links the vanilla extract rules (21 CFR 169.3) to the ice cream standards (21 CFR 135.110) when he discusses the use of vanillin to boost vanilla intensity for Category II and Category III products.

In 1980, the Flavor and Extract Manufacturers Association requested an advisory opinion from the FDA regarding the labeling of ice cream products flavored with vanilla. The FDA issued that opinion in 1981, which affirmed the conclusions of Quinn and Newberry. This advisory opinion was challenged and the conclusions were, yet again, reaffirmed in 1983<sup>6</sup>.

The FDA has been clear and consistent in its interpretations of the use of vanilla in vanilla and vanilla-flavored frozen dairy confections. Only vanilla, derived from vanilla beans, may be used in Category I ice cream. No other flavors, that allow a reduction of vanilla in finished product, may be used for Category I vanilla ice cream. The FDA has been equally clear on its position with respect to Category II vanilla flavored ice cream. The FDA used the same logic that a flavor is characterizing if it allows a reduction in the total amount of natural vanilla added. Newberry used the example of one ounce of added vanillin per gallon of single-fold extract as qualifying for Category II vanilla flavored ice cream. Any further vanillin addition beyond the allowed one ounce, or the addition of any other flavor that results in a reduction in the amount of natural vanilla used would shift a product from Category II to

Category III "Artificially Flavored". However, the flavorist has some latitude in flavor formulation for Category II products. Reducing the amount of vanillin added to vanilla extract in relation to the other added flavor compounds may provide flavor enhancement of natural extract while still meeting the FDA interpretation.

The vanilla rules are not a critical issue when vanilla bean prices are low and vanilla is readily available. The rules take on much greater importance when vanilla supply becomes short, prices skyrocket and quality is poor. The industry response to the recent vanilla crises has pointed out that the U.S. CFR regulations continue to confuse flavor vendors and ice cream manufacturers. However, when the regulations, interpretations and the advisory opinion are taken in context, there is a clear roadmap that can be used for formulation of vanilla frozen confections. The vanilla bean will live to fight another day.

## References

1. Eating It Up: Ice Cream Sales and Usage Trends. 2001. International Dairy Foods Association, 1250 N Street NW, Suite 900, Washington, D.C. 20005
2. Ice Cream Consumption in Selected Countries. 2000. Leatherhead RA, excerpted from Teagasc - Advisory - Factsheet 28: Production of Ice Cream. Irish Agriculture and Food Development Authority. Teagasc, Moorepark, Fermoy, Co. Cork. 353 (0) 25 42222
3. The United States Code of Federal Regulations. 2004. Title 21 Food and Drugs, Chapter 1. Food and Drug Administration, Department of Health and Human Services. Washington, D.C.
4. Quinn, Taylor M. May 31, 1979. Food and Drug Administration, Department of Health, Education and Welfare. Washington, D.C.
5. Newberry, R.E. October 30, 1979. Food and Drug Administration, Department of Health Education and Welfare. Washington, D.C.
6. Hile, Joseph P. February 9, 1983. Labeling of Ice Cream Products Flavored with Vanilla Docket No. 80A-0209. Food and Drug Administration, Department of Health, Education and Welfare. Washington, D.C.

## Appendix A

[Code of Federal Regulations]

[Title 21, Volume 2]

[Revised as of April 1, 2004]

From the U.S. Government Printing Office via GPO Access

[CITE: 21CFR101]

## TITLE 21--FOOD AND DRUGS

### CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

#### PART 101\_FOOD LABELING--Table of Contents Subpart B\_Specific Food Labeling Requirements



Sec. 101.22 Foods; labeling of spices, flavorings, colorings and chemical preservatives.

(a)(1) The term artificial flavor or artificial flavoring means any substance, the function of which is to impart flavor, which is not derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, fish, poultry, eggs, dairy products, or fermentation products thereof. Artificial flavor includes the substances listed in Sec. Sec. 172.515(b) and 182.60 of this chapter except where these are derived from natural sources.

(2) The term spice means any aromatic vegetable substance in the whole, broken, or ground form, except for those substances which have been traditionally regarded as foods, such as onions, garlic and celery; whose significant function in food is seasoning rather than nutritional; that is true to name; and from which no portion of any volatile oil or other flavoring principle has been removed. Spices include the spices listed in Sec. 182.10 and part 184 of this chapter, such as the following: Allspice, Anise, Basil, Bay leaves, Caraway seed, Cardamon, Celery seed, Chervil, Cinnamon, Cloves, Coriander, Cumin seed, Dill seed, Fennel seed, Fenugreek, Ginger, Horseradish, Mace, Marjoram, Mustard flour, Nutmeg, Oregano, Paprika, Parsley, Pepper, black; Pepper, white; Pepper, red; Rosemary, Saffron, Sage, Savory, Star aniseed, Tarragon, Thyme, Turmeric. Paprika, turmeric, and saffron or other spices which are also colors, shall be declared as "spice and coloring" unless declared by their common or usual name.

(3) The term natural flavor or natural flavoring means the essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product of roasting, heating or enzymolysis, which contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof, whose significant function in food is flavoring rather than nutritional. Natural flavors include the natural essence or extractives obtained from plants listed in Sec. Sec. 182.10, 182.20, 182.40, and 182.50 and part 184 of this chapter, and the substances listed in Sec. 172.510 of this chapter.

(4) The term artificial color or artificial coloring means any "color additive" as defined in Sec. 70.3(f) of this chapter.

(5) The term chemical preservative means any chemical that, when added to food, tends to prevent or retard deterioration thereof, but does not include common salt, sugars, vinegars, spices, or oils extracted from spices, substances added to food by direct exposure thereof to wood smoke, or chemicals applied for their insecticidal or herbicidal properties.

(b) A food which is subject to the requirements of section 403(k) of the act shall bear labeling, even though such food is not in package form.

(c) A statement of artificial flavoring, artificial coloring, or chemical preservative shall be placed on the food or on its

container or wrapper, or on any two or all three of these, as may be necessary to render such statement likely to be read by the ordinary person under customary conditions of purchase and use of such food. The specific artificial color used in a food shall be identified on the labeling when so required by regulation in part 74 of this chapter to assure safe conditions of use for the color additive.

(d) A food shall be exempt from compliance with the requirements of section 403(k) of the act if it is not in package form and the units thereof are so small that a statement of artificial flavoring, artificial coloring, or chemical preservative, as the case may be, cannot be placed on such units with such conspicuousness as to render it likely to be read by the ordinary individual under customary conditions of purchase and use.

(e) A food shall be exempt while held for sale from the requirements of section 403(k) of the act (requiring label statement of any artificial flavoring, artificial coloring, or chemical preservatives) if said food, having been received in bulk containers at a retail establishment, is displayed to the purchaser with either

(1) the labeling of the bulk container plainly in view or

(2) a counter card, sign, or other appropriate device bearing prominently and conspicuously the information required to be stated on the label pursuant to section 403(k).

(f) A fruit or vegetable shall be exempt from compliance with the requirements of section 403(k) of the act with respect to a chemical preservative applied to the fruit or vegetable as a pesticide chemical prior to harvest.

(g) A flavor shall be labeled in the following way when shipped to a food manufacturer or processor (but not a consumer) for use in the manufacture of a fabricated food, unless it is a flavor for which a standard of identity has been promulgated, in which case it shall be labeled as provided in the standard:

(1) If the flavor consists of one ingredient, it shall be declared by its common or usual name.

(2) If the flavor consists of two or more ingredients, the label either may declare each ingredient by its common or usual name or may state "All flavor ingredients contained in this product are approved for use in a regulation of the Food and Drug Administration." Any flavor ingredient not contained in one of these regulations, and any nonflavor ingredient, shall be separately listed on the label.

(3) In cases where the flavor contains a solely natural flavor(s), the flavor shall be so labeled, e.g., "strawberry flavor", "banana flavor", or "natural strawberry flavor". In cases where the flavor contains both a natural flavor and an artificial flavor, the flavor shall be so labeled, e.g., "natural and artificial strawberry flavor". In cases where the flavor contains a solely artificial flavor(s), the flavor shall be so labeled, e.g., "artificial strawberry flavor".

(h) The label of a food to which flavor is added shall declare the flavor in the statement of ingredients in the following way:

(1) Spice, natural flavor, and artificial flavor may be declared as "spice", "natural flavor", or "artificial flavor", or any combination thereof, as the case may be.



(2) An incidental additive in a food, originating in a spice or flavor used in the manufacture of the food, need not be declared in the statement of ingredients if it meets the requirements of Sec. 101.100(a)(3).

(3) Substances obtained by cutting, grinding, drying, pulping, or similar processing of tissues derived from fruit, vegetable, meat, fish, or poultry, e.g., powdered or granulated onions, garlic powder, and celery powder, are commonly understood by consumers to be food rather than flavor and shall be declared by their common or usual name.

(4) Any salt (sodium chloride) used as an ingredient in food shall be declared by its common or usual name "salt."

(5) Any monosodium glutamate used as an ingredient in food shall be declared by its common or usual name "monosodium glutamate."

(6) Any pyroligneous acid or other artificial smoke flavors used as an ingredient in a food may be declared as artificial flavor or artificial smoke flavor. No representation may be made, either directly or implied, that a food flavored with pyroligneous acid or other artificial smoke flavor has been smoked or has a true smoked flavor, or that a seasoning sauce or similar product containing pyroligneous acid or other artificial smoke flavor and used to season or flavor other foods will result in a smoked product or one having a true smoked flavor.

(7) Because protein hydrolysates function in foods as both flavorings and flavor enhancers, no protein hydrolysate used in food for its effects on flavor may be declared simply as "flavor," "natural flavor," or "flavoring." The ingredient shall be declared by its specific common or usual name as provided in Sec. 102.22 of this chapter.

(i) If the label, labeling, or advertising of a food makes any direct or indirect representations with respect to the primary recognizable flavor(s), by word, vignette, e.g., depiction of a fruit, or other means, or if for any other reason the manufacturer or distributor of a food wishes to designate the type of flavor in the food other than through the statement of ingredients, such flavor shall be considered the characterizing flavor and shall be declared in the following way:

(1) If the food contains no artificial flavor which simulates, resembles or reinforces the characterizing flavor, the name of the food on the principal display panel or panels of the label shall be accompanied by the common or usual name of the characterizing flavor, e.g., "vanilla", in letters not less than one-half the height of the letters used in the name of the food, except that:

(i) If the food is one that is commonly expected to contain a characterizing food ingredient, e.g., strawberries in "strawberry shortcake", and the food contains natural flavor derived from such ingredient and an amount of characterizing ingredient insufficient to independently characterize the food, or the food contains no such ingredient, the name of the characterizing flavor may be immediately preceded by the word "natural" and shall be immediately followed by the word "flavored" in letters not less than one-half the

height of the letters in the name of the characterizing flavor, e.g., "natural strawberry flavored shortcake," or "strawberry flavored shortcake".

(ii) If none of the natural flavor used in the food is derived from the product whose flavor is simulated, the food in which the flavor is used shall be labeled either with the flavor of the product from which the flavor is derived or as "artificially flavored."

(iii) If the food contains both a characterizing flavor from the product whose flavor is simulated and other natural flavor which simulates, resembles or reinforces the characterizing flavor, the food shall be labeled in accordance with the introductory text and paragraph (i)(1)(i) of this section and the name of the food shall be immediately followed by the words "with other natural flavor" in letters not less than one-half the height of the letters used in the name of the characterizing flavor.

(2) If the food contains any artificial flavor which simulates, resembles or reinforces the characterizing flavor, the name of the food on the principal display panel or panels of the label shall be accompanied by the common or usual name(s) of the characterizing flavor, in letters not less than one-half the height of the letters used in the name of the food and the name of the characterizing flavor shall be accompanied by the word(s) "artificial" or "artificially flavored", in letters not less than one-half the height of the letters in the name of the characterizing flavor, e.g., "artificial vanilla", "artificially flavored strawberry", or "grape artificially flavored".

(3) Wherever the name of the characterizing flavor appears on the label (other than in the statement of ingredients) so conspicuously as to be easily seen under customary conditions of purchase, the words prescribed by this paragraph shall immediately and conspicuously precede or follow such name, without any intervening written, printed, or graphic matter, except:

(i) Where the characterizing flavor and a trademark or brand are presented together, other written, printed, or graphic matter that is a part of or is associated with the trademark or brand may intervene if the required words are in such relationship with the trademark or brand as to be clearly related to the characterizing flavor; and

(ii) If the finished product contains more than one flavor subject to the requirements of this paragraph, the statements required by this paragraph need appear only once in each statement of characterizing flavors present in such food, e.g., "artificially flavored vanilla and strawberry".

(iii) If the finished product contains three or more distinguishable characterizing flavors, or a blend of flavors with no primary recognizable flavor, the flavor may be declared by an appropriately descriptive generic term in lieu of naming each flavor, e.g., "artificially flavored fruit punch".

(4) A flavor supplier shall certify, in writing, that any flavor he supplies which is designated as containing no artificial flavor does not, to the best of his knowledge and belief, contain any artificial flavor, and that he has added no artificial flavor to it.



The requirement for such certification may be satisfied by a guarantee under section 303(c)(2) of the act which contains such a specific statement. A flavor user shall be required to make such a written certification only where he adds to or combines another flavor with a flavor which has been certified by a flavor supplier as containing no artificial flavor, but otherwise such user may rely upon the supplier's certification and need make no separate certification. All such certifications shall be retained by the certifying party throughout the period in which the flavor is supplied and for a minimum of three years thereafter, and shall be subject to the following conditions:

(i) The certifying party shall make such certifications available upon request at all reasonable hours to any duly authorized office or employee of the Food and Drug Administration or any other employee acting on behalf of the Secretary of Health and Human Services. Such certifications are regarded by the Food and Drug Administration as reports to the government and as guarantees or other undertakings within the meaning of section 301(h) of the act and subject the certifying party to the penalties for making any false report to the government under 18 U.S.C. 1001 and any false guarantee or undertaking under section 303(a) of the act. The defenses provided under section 303(c)(2) of the act shall be applicable to the certifications provided for in this section.

(ii) Wherever possible, the Food and Drug Administration shall verify the accuracy of a reasonable number of certifications made pursuant to this section, constituting a representative sample of such certifications, and shall not request all such certifications.

(iii) Where no person authorized to provide such information is reasonably available at the time of inspection, the certifying party shall arrange to have such person and the relevant materials and records ready for verification as soon as practicable: Provided, That, whenever the Food and Drug Administration has reason to believe that the supplier or user may utilize this period to alter inventories or records, such additional time shall not be permitted. Where such additional time is provided, the Food and Drug Administration may require the certifying party to certify that relevant inventories have not been materially disturbed and relevant records have not been altered or concealed during such period.

(iv) The certifying party shall provide, to an officer or representative duly designated by the Secretary, such qualitative statement of the composition of the flavor or product covered by the certification as may be reasonably expected to enable the Secretary's representatives to determine which relevant raw and finished materials and flavor ingredient records are reasonably necessary to verify the certifications. The examination conducted by the Secretary's representative shall be limited to inspection and review of inventories and ingredient records for those certifications which are to be verified.

(v) Review of flavor ingredient records shall be limited to the qualitative formula and shall not include the quantitative formula. The person verifying the certifications may make only such notes as are necessary to enable him to verify such

certification. Only such notes or such flavor ingredient records as are necessary to verify such certification or to show a potential or actual violation may be removed or transmitted from the certifying party's place of business: Provided, That, where such removal or transmittal is necessary for such purposes the relevant records and notes shall be retained as separate documents in Food and Drug Administration files, shall not be copied in other reports, and shall not be disclosed publicly other than in a judicial proceeding brought pursuant to the act or 18 U.S.C. 1001.

(j) A food to which a chemical preservative(s) is added shall, except when exempt pursuant to Sec. 101.100 bear a label declaration stating both the common or usual name of the ingredient(s) and a separate description of its function, e.g., "preservative", "to retard spoilage", "a mold inhibitor", "to help protect flavor" or "to promote color retention".

(k) The label of a food to which any coloring has been added shall declare the coloring in the statement of ingredients in the manner specified in paragraphs (k)(1) and (k)(2) of this section, except that colorings added to butter, cheese, and ice cream, if declared, may be declared in the manner specified in paragraph (k)(3) of this section, and colorings added to foods subject to Sec. Sec. 105.62 and 105.65 of this chapter shall be declared in accordance with the requirements of those sections.

(1) A color additive or the lake of a color additive subject to certification under 721(c) of the act shall be declared by the name of the color additive listed in the applicable regulation in part 74 or part 82 of this chapter, except that it is not necessary to include the "FD&C" prefix or the term "No." in the declaration, but the term "Lake" shall be included in the declaration of the lake of the certified color additive (e.g., Blue 1 Lake). Manufacturers may parenthetically declare an appropriate alternative name of the certified color additive following its common or usual name as specified in part 74 or part 82 of this chapter.

(2) Color additives not subject to certification may be declared as "Artificial Color," "Artificial Color Added," or "Color Added" (or by an equally informative term that makes clear that a color additive has been used in the food). Alternatively, such color additives may be declared as "Colored with -----" or "----- color", the blank to be filled with the name of the color additive listed in the applicable regulation in part 73 of this chapter.

(3) When a coloring has been added to butter, cheese, or ice cream, it need not be declared in the ingredient list unless such declaration is required by a regulation in part 73 or part 74 of this chapter to ensure safe conditions of use for the color additive. Voluntary declaration of all colorings added to butter, cheese, and ice cream, however, is recommended.

[42 FR 14308, Mar. 15, 1977, as amended at 44 FR 3963, Jan. 19, 1979; 44 FR 37220, June 26, 1979; 54 FR 24891, June 12, 1989; 58 FR 2875, Jan. 6, 1993; 63 FR 14818, Mar. 27, 1998]



## Appendix B

The author has not included Sections 169.115 to 169.150 because they are not pertinent to the vanilla discussion.

[Code of Federal Regulations]

[Title 21, Volume 2]

[Revised as of April 1, 2004]

From the U.S. Government Printing Office via GPO Access

[CITE: 21CFR169]

## TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION,  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
(CONTINUED)PART 169\_FOOD DRESSINGS AND FLAVORINGS  
Subpart A\_General Provisions

## Sec. 169.3 Definitions.

Subpart B\_Requirements for Specific Standardized Food  
Dressings and Flavorings

- 169.115 French dressing.
- 169.140 Mayonnaise.
- 169.150 Salad dressing.
- 169.175 Vanilla extract.
- 169.176 Concentrated vanilla extract.
- 169.177 Vanilla flavoring.
- 169.178 Concentrated vanilla flavoring.
- 169.179 Vanilla powder.
- 169.180 Vanilla-vanillin extract.
- 169.181 Vanilla-vanillin flavoring.
- 169.182 Vanilla-vanillin powder.

Authority: 21 U.S.C. 321, 341, 343, 348, 371, 379e.

Source: 42 FR 14481, Mar. 15, 1977, unless otherwise noted.

## Subpart A\_General Provisions

## Sec. 169.3 Definitions.

For the purposes of this part:

- (a) The term vanilla beans means the properly cured and dried fruit pods of *Vanilla planifolia* Andrews and of *Vanilla tahitensis* Moore.
- (b) The term unit weight of vanilla beans means, in the case of vanilla beans containing not more than 25 percent moisture, 13.35 ounces of such beans; and, in the case of vanilla

beans containing more than 25 percent moisture, it means the weight of such beans equivalent in content of moisture-free vanilla-bean solids to 13.35 ounces of vanilla beans containing 25 percent moisture. (For example, one unit weight of vanilla beans containing 33.25 percent moisture amounts to 15 ounces.) The moisture content of vanilla beans is determined by the method prescribed in Official Methods of Analysis of the Association of "Official Analytical Chemists," 13th Ed. (1980), sections 7.004 and 7.005, which is incorporated by reference, except that the toluene used is blended with 20 percent by volume of benzene and the total distillation time is 4 hours. Copies of the material incorporated by reference may be obtained from the Association of Official Analytical Chemists International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877-2504, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC. To prepare samples for analysis, the pods are chopped into pieces approximately 1/4-inch in longest dimension, using care to avoid moisture change.

(c) The term unit of vanilla constituent means the total sapid and odorous principles extractable from one unit weight of vanilla beans, as defined in paragraph (b) of this section, by an aqueous alcohol solution in which the content of ethyl alcohol by volume amounts to not less than 35 percent.

[42 FR 14481, Mar. 15, 1977, as amended at 47 FR 11834, Mar. 19, 1982; 49 FR 10103, Mar. 19, 1984; 54 FR 24896, June 12, 1989; 63 FR 14035, Mar. 24, 1998]

Subpart B\_Requirements for Specific Standardized Food  
Dressings and Flavorings

## Sec. 169.175 Vanilla extract.

(a) Vanilla extract is the solution in aqueous ethyl alcohol of the sapid and odorous principles extractable from vanilla beans. In vanilla extract the content of ethyl alcohol is not less than 35 percent by volume and the content of vanilla constituent, as defined in Sec. 169.3(c), is not less than one unit per gallon. The vanilla constituent may be extracted directly from vanilla beans or it may be added in the form of concentrated vanilla extract or concentrated vanilla flavoring or vanilla flavoring concentrated to the semisolid form called vanilla oleo-resin. Vanilla extract may contain one or more of the following optional ingredients:

- (1) Glycerin.
- (2) Propylene glycol.
- (3) Sugar (including invert sugar).
- (4) Dextrose.
- (5) Corn syrup (including dried corn syrup).
- (b)(1) The specified name of the food is "Vanilla extract" or "Extract of vanilla".
- (2) When the vanilla extract is made in whole or in part by dilution of vanilla oleoresin, concentrated vanilla extract, or concentrated vanilla flavoring, the label shall bear the statement



"Made from -----" or "Made in part from -----", the blank being filled in with the name or names "vanilla oleoresin", "concentrated vanilla extract", or "concentrated vanilla flavoring", as appropriate. If the article contains two or more units of vanilla constituent, the name of the food shall include the designation "---fold", the blank being filled in with the whole number (disregarding fractions) expressing the number of units of vanilla constituent per gallon of the article.

(3) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the labeling required by paragraph (b)(2) of this section shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.

(c) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14479, Mar. 15, 1977, as amended at 58 FR 2886, Jan. 6, 1993]

#### Sec. 169.176 Concentrated vanilla extract.

(a) Concentrated vanilla extract conforms to the definition and standard of identity and is subject to any requirement for label statement of ingredients prescribed for vanilla extract by Sec. 169.175, except that it is concentrated to remove part of the solvent, and each gallon contains two or more units of vanilla constituent as defined in Sec. 169.3(c). The content of ethyl alcohol is not less than 35 percent by volume.

(b) The specified name of the food is "Concentrated vanilla extract ---fold" or "---fold concentrated vanilla extract", the blank being filled in with the whole number (disregarding fractions) expressing the number of units of vanilla constituent per gallon of the article. (For example, "Concentrated vanilla extract 2-fold".)

[42 FR 14479, Mar. 15, 1977, as amended at 58 FR 2886, Jan. 6, 1993]

#### Sec. 169.177 Vanilla flavoring.

(a) Vanilla flavoring conforms to the definition and standard of identity and is subject to any requirement for label statement of ingredients prescribed for vanilla extract by Sec. 169.175, except that its content of ethyl alcohol is less than 35 percent by volume.

(b) The specified name of the food is "Vanilla flavoring".

[42 FR 14479, Mar. 15, 1977, as amended at 58 FR 2886, Jan. 6, 1993]

#### Sec. 169.178 Concentrated vanilla flavoring.

(a) Concentrated vanilla flavoring conforms to the definition and standard of identity and is subject to any requirement for

label statement of ingredients prescribed for vanilla flavoring by Sec. 169.177, except that it is concentrated to remove part of the solvent, and each gallon contains two or more units of vanilla constituent as defined in Sec. 169.3(c).

(b) The specified name of the food is "Concentrated vanilla flavoring ---fold" or "---fold concentrated vanilla flavoring", the blank being filled in with the whole number (disregarding fractions) expressing the number of units of vanilla constituent per gallon of the article. (For example, "Concentrated vanilla flavoring 3-fold".)

[42 FR 14479, Mar. 15, 1977, as amended at 58 FR 2886, Jan. 6, 1993]

#### Sec. 169.179 Vanilla powder.

(a) Vanilla powder is a mixture of ground vanilla beans or vanilla oleoresin or both, with one or more of the following optional blending ingredients:

- (1) Sugar.
- (2) Dextrose.
- (3) Lactose.
- (4) Food starch (including food starch-modified as prescribed in Sec. 172.892 of this chapter).
- (5) Dried corn syrup.
- (6) Gum acacia.

Vanilla powder may contain one or any mixture of two or more of the anticaking ingredients specified in paragraph

(b) of this section, but the total weight of any such ingredient or mixture is not more than 2 percent of the weight of the finished vanilla powder. Vanilla powder contains in each 8 pounds not less than one unit of vanilla constituent, as defined in Sec. 169.3(c).

(b) The anticaking ingredients referred to in paragraph (a) of this section are:

- (1) Aluminum calcium silicate.
- (2) Calcium silicate.
- (3) Calcium stearate.
- (4) Magnesium silicate.
- (5) Tricalcium phosphate.

(c)(1) The specified name of the food is "Vanilla powder --fold" or "---fold vanilla powder", except that if sugar is the optional blending ingredient used, the word "sugar" may replace the word "powder". The blank in the name is filled in with the whole number (disregarding fractions) expressing the number of units of vanilla constituent per 8 pounds of the article. However, if the strength of the article is less than 2-fold, the term "---fold" is omitted from the name.

(2) The label of vanilla powder shall bear the common names of any of the optional ingredients specified in paragraphs (a) and (b) of this section that are used, except that where the alternative name "Vanilla sugar" is used for designating the food it is not required that sugar be named as an optional ingredient.



(3) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the labeling required by paragraph (c)(2) of this section shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.

(d) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14479, Mar. 15, 1977, as amended at 58 FR 2887, Jan. 6, 1993]

#### Sec. 169.180 Vanilla-vanillin extract.

(a) Vanilla-vanillin extract conforms to the definition and standard of identity and is subject to any requirement for label statement of ingredients prescribed for vanilla extract by Sec. 169.175, except that for each unit of vanilla constituent, as defined in Sec. 169.3(c), contained therein, the article also contains not more than 1 ounce of added vanillin.

(b) The specified name of the food is "Vanilla-vanillin extract ---fold" or "---fold vanilla-vanillin extract", followed immediately by the statement "contains vanillin, an artificial flavor (or flavoring)". The blank in the name is filled in with the whole number (disregarding fractions) expressing the sum of the number of units of vanilla constituent plus the number of ounces of added vanillin per gallon of the article. However, if the strength of the article is less than 2-fold, the term "---fold" is omitted from the name.

[42 FR 14479, Mar. 15, 1977, as amended at 58 FR 2887, Jan. 6, 1993]

#### Sec. 169.181 Vanilla-vanillin flavoring.

(a) Vanilla-vanillin flavoring conforms to the definition and standard of identity and is subject to any requirement for label statement of ingredients prescribed for vanilla-vanillin extract by Sec. 169.180, except that its content of ethyl alcohol is less than 35 percent by volume.

(b) The specified name of the food is "Vanilla-vanillin flavoring---fold" or "---fold vanilla-vanillin flavoring", followed immediately by the statement "contains vanillin, an artificial flavor (or flavoring)". The blank in the name is filled in with the whole number (disregarding fractions) expressing the sum of the number of units of vanilla constituent plus the number of ounces of added vanillin per gallon of the article. However, if the strength of the article is less than 2-fold, the term "---fold" is omitted from the name.

[42 FR 14479, Mar. 15, 1977, as amended at 58 FR 2887, Jan. 6, 1993]

#### Sec. 169.182 Vanilla-vanillin powder.

(a) Vanilla-vanillin powder conforms to the definition and standard of identity and is subject to any requirement for label statement of ingredients prescribed for vanilla powder by Sec. 169.179, except that for each unit of vanilla constituent as defined in Sec. 169.3(c) contained therein, the article also contains not more than 1 ounce of added vanillin.

(b) The specified name of the food is "Vanilla-vanillin powder ---fold" or "---fold vanilla-vanillin powder", followed immediately by the statement "contains vanillin, an artificial flavor (or flavoring)". If sugar is the optional blending ingredient used, the word "sugar" may replace the word "powder" in the name. The blank in the name is filled in with the whole number (disregarding fractions) expressing the sum of the number of units of vanilla constituent plus the number of ounces of added vanillin per 8 pounds of the article. However, if the strength of the article is less than 2-fold the term "---fold" is omitted from the name.

[42 FR 14479, Mar. 15, 1977, as amended at 58 FR 2887, Jan. 6, 1993]

### Appendix C

Author has not included Sections 135.110 (a) through (e) because they are not pertinent to the vanilla discussion.

[Code of Federal Regulations]

[Title 21, Volume 2]

[Revised as of April 1, 2004]

From the U.S. Government Printing Office via GPO Access

[CITE: 21CFR135]

#### TITLE 21--FOOD AND DRUGS

#### CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

#### PART 135\_FROZEN DESSERTS--Table of Contents

#### Subpart B\_Requirements for Specific Standardized Frozen Desserts

#### Sec. 135.110 Ice cream and frozen custard.

(f) Nomenclature.

(1) The name of the food is "ice cream"; except that when the egg yolk solids content of the food is in excess of that specified for ice cream by paragraph (a) of this section, the name of



the food is "frozen custard" or "french ice cream" or "french custard ice cream".

(2)(i) If the food contains no artificial flavor, the name on the principal display panel or panels of the label shall be accompanied by the common or usual name of the characterizing flavor, e.g., "vanilla", in letters not less than one-half the height of the letters used in the words "ice cream".

(ii) If the food contains both a natural characterizing flavor and an artificial flavor simulating it, and if the natural flavor predominates, the name on the principal display panel or panels of the label shall be accompanied by the common name of the characterizing flavor, in letters not less than one-half the height of the letters used in the words "ice cream", followed by the word "flavored", in letters not less than one-half the height of the letters in the name of the characterizing flavor, e.g., "Vanilla flavored", or "Peach flavored", or "Vanilla flavored and Strawberry flavored".

(iii) If the food contains both a natural characterizing flavor and an artificial flavor simulating it, and if the artificial flavor predominates, or if artificial flavor is used alone the name on the principal display panel or panels of the label shall be accompanied by the common name of the characterizing flavor in letters not less than one-half the height of the letters used in the words "ice cream", preceded by "artificial" or "artificially flavored", in letters not less than one-half the height of the letters in the name of the characterizing flavor, e.g., "artificial Vanilla", or "artificially flavored Strawberry" or "artificially flavored Vanilla and artificially flavored Strawberry".

(3)(i) If the food is subject to the requirements of paragraph (f)(2)(ii) of this section or if it contains any artificial flavor not simulating the characterizing flavor, the label shall also bear the words "artificial flavor added" or "artificial ----- flavor added", the blank being filled with the common name of the flavor simulated by the artificial flavor in letters of the same size and prominence as the words that precede and follow it.

(ii) Wherever the name of the characterizing flavor appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the words prescribed by this paragraph shall immediately and conspicuously precede or follow such name, in a size reasonably related to the prominence of the name of the characterizing flavor and in any event the size of the type is not less than 6-point on packages containing less than 1 pint, not less than 8-point on packages containing at least 1 pint but less than one-half gallon, not less than 10-point on packages containing at least one-half gallon but less than 1 gallon, and not less than 12-point on packages containing 1 gallon or over: Provided, however, That where the characterizing flavor and a trademark or brand are presented together, other written, printed, or graphic matter that is a part of or is associated with the trademark or brand, may intervene if the required words are in such relationship with the trademark or brand as to be clearly related to the characterizing flavor: And provided further, That if the finished product contains more than one flavor of ice cream

subject to the requirements of this paragraph, the statements required by this paragraph need appear only once in each statement of characterizing flavors present in such ice cream, e.g., "Vanilla flavored, Chocolate, and Strawberry flavored, artificial flavors added".

(4) If the food contains both a natural characterizing flavor and an artificial flavor simulating the characterizing flavor, any reference to the natural characterizing flavor shall, except as otherwise authorized by this paragraph, be accompanied by a reference to the artificial flavor, displayed with substantially equal prominence, e.g., "strawberry and artificial strawberry flavor".

(5) An artificial flavor simulating the characterizing flavor shall be deemed to predominate:

(i) In the case of vanilla beans or vanilla extract used in combination with vanillin if the amount of vanillin used [[Page 368]] is greater than 1 ounce per unit of vanilla constituent, as that term is defined in Sec. 169.3(c) of this chapter.

(ii) In the case of fruit or fruit juice used in combination with artificial fruit flavor, if the quantity of the fruit or fruit juice used is such that, in relation to the weight of the finished ice cream, the weight of the fruit or fruit juice, as the case may be (including water necessary to reconstitute partially or wholly dried fruits or fruit juices to their original moisture content) is less than 2 percent in the case of citrus ice cream, 6 percent in the case of berry or cherry ice cream, and 10 percent in the case of ice cream prepared with other fruits.

(iii) In the case of nut meats used in combination with artificial nut flavor, if the quantity of nut meats used is such that, in relation to the finished ice cream the weight of the nut meats is less than 2 percent.

(iv) In the case of two or more fruits or fruit juices, or nut meats, or both, used in combination with artificial flavors simulating the natural flavors and dispersed throughout the food, if the quantity of any fruit or fruit juice or nut meat is less than one-half the applicable percentage specified in paragraph (e)(5) (ii) or (iii) of this section. For example, if a combination ice cream contains less than 5 percent of bananas and less than 1 percent of almonds it would be "artificially flavored banana-almond ice cream". However, if it contains more than 5 percent of bananas and more than 1 percent of almonds it would be "banana-almond flavored ice cream".

(6) If two or more flavors of ice cream are distinctively combined in one package, e.g., "Neapolitan" ice cream, the applicable provisions of this paragraph shall govern each flavor of ice cream comprising the combination.

(7) Until September 14, 1998, when safe and suitable sweeteners other than nutritive carbohydrate sweeteners are used in the food, their presence shall be declared by their common or usual name on the principal display panel of the label as part of the statement of identity in letters that shall be no less than one-half the size of the type used in the term "ice cream" but in any case no smaller than one-sixteenth of an inch. If the



food purports to be or is represented for special dietary use, it shall bear labeling in accordance with the requirements of part 105 of this chapter.

(g) Label declaration. Each of the ingredients used shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that the sources of milkfat or milk solids not fat may be declared in descending order of predominance either by the use of all the terms "milkfat and nonfat milk" when one or any combination of two or more of the ingredients listed in Sec. 101.4(b)(3), (b)(4), (b)(8), and (b)(9) of this chapter are used or, alternatively, as permitted in

Sec. 101.4 of this chapter. Under section 403(k) of the Federal Food, Drug, and Cosmetic Act, artificial color need not be declared in ice cream, except as required by Sec. 101.22(c) or (k) of this chapter. Voluntary declaration of all colors used in ice cream and frozen custard is recommended.

[43 FR 4598, Feb. 3, 1978, as amended at 45 FR 63838, Sept. 26, 1980; 46 FR 44433, Sept. 4, 1981; 47 FR 11826, Mar. 19, 1982; 49 FR 10096, Mar. 19, 1984; 54 FR 24894, June 12, 1989; 58 FR 2896, Jan. 6, 1993; 59 FR 47079, Sept. 14, 1994; 63 FR 14035, Mar. 24, 1998; 63 FR 14818, Mar. 27, 1998]